

# **Exhibit 15**

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# Study Finds Association Between Genital Talc Use and Increased Risk of Ovarian Cancer

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## ASCO Perspective

"This study underscores the potential risks associated with intimate care products, particularly genital talc. The evidence adds to a growing body of literature that suggests such products could contribute to an increased risk of ovarian cancer, especially among frequent users and those using these products in their 20s and 30s," said ASCO Expert Fumiko Chino, MD, Radiation Oncologist at Memorial Sloan Kettering Cancer.

- **Focus:** This study examines the association between the use of intimate care products, specifically genital talc and douching, and the risk of hormone-related cancers such as ovarian, breast, and uterine cancers, correcting for potential biases like recall bias and exposure misclassification.
- **Population:** The study involved 50,884 women from the Sister Study cohort, all of whom had a sister diagnosed with breast cancer, providing a unique perspective on the genetic predisposition to hormone-related cancers.
- **Main Takeaway:** Genital talc use was found to be positively associated with the risk of ovarian cancer across multiple scenarios, even after adjusting for potential reporting biases and misclassification. The association was particularly strong among women who used talc frequently or especially during periods of significant hormonal changes or reproductive activity.
- **Significance:** These findings contribute significant insights into the ongoing debate about the safety of intimate care products and underscore the need for further research and potential reevaluation of these products' safety.

**ALEXANDRIA, Va.** — A new study published today in the *Journal of Clinical Oncology* provides

compelling evidence that genital talc use is associated with an increased risk of ovarian cancer. This extensive analysis, part of the Sister Study cohort, revisits the association between intimate care products and cancer, incorporating rigorous adjustments for biases that might have affected earlier studies.

"Despite challenges in assessing exposure history and biases inherent in retrospective data, our findings are robust, showing a consistent association between genital talc use and ovarian cancer," said lead study author Katie M. O'Brien, Ph.D., researcher at the Epidemiology Branch of the National Institute of Environmental Health Sciences. "This study leverages detailed lifetime exposure histories, and the unique design of the Sister Study, to provide more reliable evidence that supports a potential association between long-term and frequent genital talc use and ovarian cancer."

The study utilized quantitative bias analysis to assess potential errors in reporting and analyzed data from a cohort of women who were initially cancer-free, tracked for their use of intimate care products like genital talc and douching.

### **Key Findings**

- Persistent positive association between genital talc use and ovarian cancer, with the highest risks observed in frequent and long-term users.
- No significant associations found between genital talc use or douching and breast or uterine cancer.
- Douching showed a possible association with ovarian cancer, warranting further investigation.

### **Next Steps**

The researchers advocate for continued examination of the specific chemicals in intimate care products that may influence cancer risk and encourage further studies to replicate these findings in different populations.

### **Funding**

This research was supported by the Intramural Research Program of the National Institute of Environmental Health Sciences, National Institutes of Health.

**For Your Readers:**

- [Ovarian Cancer](#)

**ATTRIBUTION TO THE JOURNAL OF CLINICAL ONCOLOGY IS REQUESTED IN ALL COVERAGE.**

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**ABSTRACT****Intimate care products and incidence of hormone-related cancers: A quantitative bias analysis**

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**Abstract**

**Purpose** Intimate care products may contain substances associated with increased risk of hormone-related cancers. The relationship between genital talc use and ovarian cancer, in particular, has been well-studied, but concerns about recall bias and exposure misclassification have precluded conclusions. We examined the association between intimate care products and female hormone-related cancers, accounting for potential biases, using data from a US-based cohort study.

**Participants and Methods** The Sister Study enrolled 50,884 women who had a sister with breast cancer. Data on genital talc use and douching were collected at enrollment (2003-09) and follow-up (2017-19). We used Cox proportional hazards models to estimate hazard ratios

(HRs) for associations between intimate care product use and breast, ovarian, and uterine cancer. To account for potential exposure misclassification and recall bias, we conducted quantitative bias analyses under various exposure re-assignment assumptions.

**Results** Across considered scenarios, 41-64% of participants douched and 35-56% used genital talc. In models adjusted for exposure misclassification, genital talc use was positively associated with ovarian cancer (HR range 1.17-3.34) Frequent douching and douching during young adulthood were positively associated with ovarian cancer, but neither douching nor talc were associated with breast or uterine cancer. Differential reporting of talc use by cases and non-cases likely produces positive biases, but correcting for error still resulted in HRs above 1.0. For example, HR=1.40, CI: 1.04-1.89 when 25% of exposed cases and 10% of unexposed non-cases had talc status re-assigned.

**Conclusions** While results show how differential recall would upwardly bias estimates, corrected results support a positive association between use of intimate care products, including genital talc, and ovarian cancer.

## About ASCO:

Founded in 1964, the American Society of Clinical Oncology, Inc. (ASCO®) is committed to the principle that knowledge conquers cancer. Together with the Association for Clinical Oncology, ASCO represents nearly 50,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of high quality, equitable patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is healthy. Conquer Cancer, the ASCO Foundation, supports ASCO by funding groundbreaking research and education across cancer's full continuum. Learn more at [www.ASCO.org](http://www.ASCO.org), explore patient education resources at [www.Cancer.Net](http://www.Cancer.Net), and follow us on [Facebook](#), [Twitter](#), [LinkedIn](#), [Instagram](#), and [YouTube](#).

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